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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,975	09/18/2003	Ingo Tamm	BURNHAM.005A	5524

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
BROWN, TIMOTHY M	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,975	TAMM ET AL.	
	Examiner	Art Unit	
	Timothy M. Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 11-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *30 August 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received January 13, 2006. Claims 1-34 are pending. Claims 9 and 10 are under examination.

Elections/Restrictions

Applicant's election of Group III, claims 9 and 10, in the reply filed on January 13, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title describes a method for the "use of hepatitis B x-interacting protein (HBXIP) in modulation of apoptosis." However, the invention is drawn to a compound that inhibits Survivin. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 9 is for a compound that inhibits Survivin in the presence of hepatitis B x-interacting protein (HBXIP). Unpurified anti-Survivin antibody is a compound that

can inhibit Survivin as claimed. Because serum is a product of nature, claim 9 is rejected for being drawn to non-statutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite for reciting "in the presence of HBXIP." This language fails to indicate the nature of the activity of the claimed compound. It is unclear whether the compound inhibits Survivin transcription/translation, or interferes with the Survivin/HBXIP interaction. "[I]n the presence of HBXIP" also fails to indicate whether the compound is directed to the binding or active site of HBXIP protein with which Survivin interacts. Claims 9 and 10 therefore fail to clearly set forth the metes and bounds of the invention. For examination purposes, the claims are interpreted as drawn to a compound that inhibits the interaction of Survivin and HBXIP.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not provide an enabling description that is commensurate in scope with the claims. The specification enables anti-sense Survivin oligonucleotides and anti-Survin

antibodies as compounds that inhibit Survivin in the presence of HBXIP. However, undue experimentation would be required to make and use other compounds which are embraced by the claims.

Undue experimentation is defined by the following factors: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

Here, the breadth of the claims embrace small molecules and competitive peptide ligands that inhibit the interaction and/or catalytic activity of Survivin and HBXIP. At the time this application was filed, Survivin had been associated with apoptosis resistance in some forms of cancer. It was also recognized that Survivin's anti-apoptic activity was linked to the inhibition of certain caspases.[1] However, the Survivin/HBXIP interaction was not known in the art. Thus, developing multiple small molecule compounds and peptide ligands that interfere with the binding and/or active sites of the Survivin and HBXIP proteins would have been completely unpredictable when this application was filed. The difficulty of developing the claimed small molecules is compound by the fact that identifying compounds that have the precise conformation for interacting with a protein active site also lacks any sense of predictability.

The skilled artisan would therefore have to rely heavily on the specification in order to produce the small molecule inhibitors embraced by the claims.

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[1] See e.g. Reed, J.C. "The Survivin saga goes in vivo" Journ. Clin. Investig. October 2001; 108 (7): 965-969.

The content of the specification discloses, and enables, Survivin antisense oligonucleotides and anti-Survivin antibodies as compounds that inhibit Survivin in the presence of HBXIP. Although the specification teaches a screening method for identifying Survivin inhibitors, it fails enable small molecules and/or peptide ligands that inhibit the Survivin/HBXIP interaction. The only teachings in the specification that relate to small molecules discuss the use of pharmaceutical carriers as a means for administering a hypothetical small molecule inhibitor. There is no disclosure of the active sites, let alone their conformation, which modulate the activity of Survivin. Without any general information on the properties the candidate compounds would need to possess, or the nature of the Survivin/HBXIP interaction, the skilled artisan would have to screen an extremely large number of compounds. This level of experimentation would certainly be undue. Therefore, the skilled artisan would have to invest undue experimentation in order to make and use small molecule Survivin/HBXIP inhibitors as claimed.

Claims 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants claim any compound that inhibits Survivin in the presence of HBXIP. The specification however only discloses antisense oligonucleotides and anti-Survivin antibodies as compounds that possess the claimed inhibitory activity. However, there is no teaching of small molecules or competitive peptide ligands that inhibit the Survivin/HBXIP interaction. Moreover, the skilled artisan could not conclude that the inventors were in possession of such

inhibitors since the domains that control the Survivin/HBXIP interaction were not yet known, let alone characterized. Thus, the content specification does not show that the inventors were in possession of small molecule and peptide Survivin inhibitors as provided in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Banks et al. "Survivin does not inhibit caspase-3 activity" Blood December 2000; 96 (12): 4002-4003).

Applicants claim any compound that inhibits Survivin in the presence of HBXIP. According to the specification, anti-Survivin antibody is one such compound (para. 0052). Therefore, by disclosing anti-Survivin antibody (see Fig. 1c), Banks et al. anticipate the subject matter of claims 9 and 10.

Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Yagihashi et al. "Detection of Anti-Survivin Antibody in Gastrointestinal Cancer Patients" Clin Chem Sept. 2001; 47 (9): 1729-1731).

Applicants claims embrace anti-Survivin antibody as noted above. Therefore, by disclosing human sera comprising anti-Survivin antibody (see e.g. beginning of p. 1730), Yagahashi et al. anticipate the subject matter of claims 9 and 10.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb

JAMES HOUSEL 2/21/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

TMB 6/19/06